

BEST AVAILABLE COPY

THE COMPLETE CELL SOLUTION

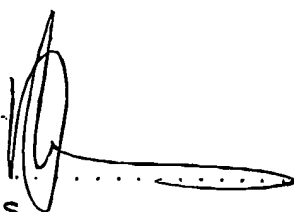


ecacc
European Collection
of Cell Cultures

Centre for Applied Microbiology and Research
and
European Collection of Cell Cultures

This document certifies that
Hybridoma LM04 16H2.C1.B8
Deposit Reference 03052001

has been accepted as a patent deposit, in accordance with
The Budapest Treaty of 1977,
with the European Collection of Cell Cultures on
20 May 2003


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Dr D H Lewis
General Manager
ECACC

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

TO
DR L WILSON
WALTER & ELISA HALL INSTITUTE OF ME

INTERNATIONAL FORM

POST OFFICE
ROYAL MELBOURNE HOSPITAL
PARKVILLE
VIC 3050
AUSTRALIA

NAME AND ADDRESS
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the
DEPOSITOR:

LM04 16H2.C1.B8

Accession number given by the
INTERNATIONAL DEPOSITARY AUTHORITY:

03052001

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

- ☒ A scientific description
☐ A proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above,
which was received by it on 20 May 2003 (date of the original deposit)¹

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International
Depositary Authority on (date of the original deposit) and
A request to convert the original deposit to a deposit under the Budapest Treaty
was received by it on (date of receipt of request for conversion)

IV. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Dr D H Lewis

Address: ECACC
CARR
Porton Down
Salisbury SP4 0JG

Signature(s) of person(s) having the power
to represent the International Depositary
Authority or of authorized official(s):

Date: 16/3/04

¹ Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
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INTERNATIONAL FORM

TO
DR L WILSON
WALTER & ELISA HALL INSTITUTE OF ME

POST OFFICE
ROYAL MELBOURNE HOSPITAL
PARKVILLE
VIC 3050
AUSTRALIA

NAME AND ADDRESS OF THE PARTY
TO WHOM THE VIABILITY OF STATEMENT
IS ISSUED

VIABILITY STATEMENT
Issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identifier on the following page

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
<p>me: DR L WILSON WALTER & ELISA HALL INSTITUTE OF ME</p> <p>Address: POST OFFICE ROYAL MELBOURNE HOSPITAL PARKVILLE VIC 3050 AUSTRALIA</p>	<p>Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: 03052001</p> <p>Date of the deposit or of the transfer: 20 May 2003</p>
II. VIABILITY STATEMENT	
<p>The viability of the microorganism identified under II above was tested on 20 May 2003. On that date, the said microorganism was</p> <p><input checked="" type="checkbox"/> , viable</p> <p><input type="checkbox"/> , no longer viable</p>	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
 - 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
 - 3 Mark with a cross the applicable box.
- Form BP/4 (first page)

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED	
II. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Dr D H Lewis ECACC CAMR Address: Porton Down Salisbury Wiltshire SP4 0JG	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date: 16/3/84

4 Fill in if the information has been requested and if the results of the test were negative.

Form BP/9 (second and last page)

Certificate of Analysis

Product Description LM04 16H2.CL.B8
Lot Number 03/K/011

Test Description: Cell Count, Viability and confluency of cells on resuscitation from frozen.

Acceptance Criterion/Specification: were judged acceptable if they meet two of the following criteria:

- >70% viable cells
- $>2 \times 10^6$ viable cells/ml
- confluent in 2 days

Date: 09/01/04

Result:

Viable Cell Count: 1.78×10^7 cells/ml
Percentage Viability: 41%
Confluent in: Good Growth in 2 days

Test Description: The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.
SOP QC/MYCO/01

Acceptance Criterion/Specification: All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.

The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.

Test Number: 28717

Date: 09/02/04

Result:

Positive Control: Positive
Negative Control: Negative
Test Result: Negative
Overall Result: PASS

Authorised by Alun Wilson Acting ECACC, Head of Quality, 18/2/04 Date

Certificate of Analysis

Product Description
Lot Number

LM04 16H2.CL.B8
03/K/011

Test Description: Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.
SOP QC/MYCO/07

Acceptance Criterion/Specification: The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

Test Number: 28717
Date: 19/01/04
Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Test Description: Sterility Testing of Cell Banks (SOP ECACC/048)

Acceptance Criterion/Specification: All positive controls (*Bacillus subtilis* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

Test Number: 28717
Date: 12/12/03
Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Test Description: Monoclonal Antibody Isotyping.
SOP ECACC/019

Acceptance Criterion/Specification: The light chain and isotype detected match those expected. A band appears in the positive control region.

Test Number: 28717
Date: 22/01/04
Result:

Positive Control:	Positive
Expected Result:	Unknown
Test Result:	IgG2a

Authorised by Chin Wilson Acting ECACC, Head of Quality. 18/2/04 Date